GeneSolve Program Guidelines

A. Introduction and Background

Genome British Columbia (Genome BC) leads genomics innovation on Canada's West Coast and facilitates the adoption and integration of genomics into society. Genomics[1] has revolutionized our understanding about the genetic makeup of life forms on earth and is having significant impact on human health, food and our natural resources. By supporting genomics research, Genome BC aims to apply the power of genomics to pressing societal and economic challenges. A recognized catalyst for government and industry, Genome BC invests in research to address challenges in BC's Health, Agrifood and Natural Resources sectors. Examples of research projects supported by Genome BC can be found at: https://www.genomebc.ca/funding/search-projects/.

Genome BC aims to support the development of genomics research into practical applications that provide innovative and effective solutions to challenges, which may lead to enhanced competitiveness and sustainability across the key sectors. With this vision, Genome BC created GeneSolve, a funding program that co-invests with Sector Partner organizations to apply genomics for solving sector challenges.

B. Program Objectives

The overarching objective of GeneSolve is to facilitate adoption of genomics across key BC sectors, such as health, forestry, agriculture & agrifood, fisheries & aquaculture, mining, energy and the environment. The goals of the program are to:

- enable genomics derived and genomics enabled solutions to sector challenges;
- support foundational, applied and translational research that can address societal and/or economic challenges in BC and beyond.

Strategically positioned within Genome BC's programmatic offerings to fund genomics research and innovation, it is anticipated that partnerships supported through GeneSolve will lead to opportunities for implementation, translation or commercialization of the project outcomes. GeneSolve projects may lead to follow-on project opportunities funded by Genome Canada, Genome BC or other organizations and agencies.

C. Eligibility and Role of Applicants

There are two categories of GeneSolve applicants: **Sector Partners** and **Academic Partners.**

Sector Partners

A **Sector Partner** is defined as an organization that intends and has the capability to put the resulting project deliverables into use (in internal operations, by commercialization, or otherwise making them available to ultimate users).

[1]The term genomics is specifically defined here as the comprehensive study, using high throughput cutting edge technologies, of the genetic information of a cell or an organism. This includes the function of specific genes, gene clusters, their interactions with each other or the surrounding environment as well as regulation. For ease of reference, but not limited to, it includes related disciplines such as bioinformatics, epigenomics, metabolomics, metagenomics, proteomics, and transcriptomics.

Examples of Sector Partners may include: companies, industry consortia, government departments or agencies, or not-for-profits with a credible plan for exploiting project outcomes for the socio-economic benefits of BC, Canada or the world. The Sector Partner can apply from any jurisdiction around the world and does not have to have headquarters or operations in BC as long as benefits to BC are significant and clear.

To participate in the GeneSolve program, the Sector Partner must:

1. present a sector challenge, the solution to which would bring socio-economic benefits for the sector and BC and which either: (a) requires genomics or (b) advances the application of genomics;
2. have the required capability (e.g. research, technical, management, financial and leadership) to implement the solution to solve the sector challenge;
3. provide a letter of commitment for co-funding and supporting financial documents[2] confirming at least 50% of the funding for the project;
4. accept Genome BC's data sharing and release policy; and
5. accept Genome BC's Intellectual Property policy (see Section D).

Academic Partners

An **Academic Partner** is a person with a faculty appointment/permanent position at an accredited BC institution or affiliated, non-commercial entity (see below). Please note that an Academic Partner cannot be a Sector Partner on the same project or the owner of or employed by a Sector Partner.

To be eligible for the GeneSolve program, the Academic Partner:

1. Must be appointed as faculty or hold a permanent position at one of the following types of BC institutions:
   - Post-secondary institutions or their affiliated hospitals or research institutes.
   - Laboratories of federal government departments or agencies.
   - Non-governmental, not-for-profit organizations (including community or charitable organizations) with a clear and explicit research or knowledge translation mandate.
2. Must be eligible to administer a research account through their institution.
3. Must declare any actual or perceived conflict of interest with the Sector Partner.

Potential applicants are encouraged to talk to a Genome BC Research and Innovation Manager to help assess fit with the program before applying. Research and Innovation Managers can be contacted directly or through genesolve@genomebc.ca.

In order to be eligible for GeneSolve, projects must meet the following criteria.

Project Eligibility:

1. **Strategic Alignment:**
   a. How well does the proposed project align with Genome BC's strategic goals for the sector? Note that as part of this assessment, Genome BC will consider its funded project portfolio and possible overlap.

[2] Please see the section A of Appendix 2 of this guideline.

b. The proposed solution has a clear basis in genomics (genomics-derived or genomics-enabled).

2. **Partnership:**
   a. Project responds to an opportunity or challenge clearly defined by the Sector Partner(s).
   b. Project is a partnership of an Academic and a Sector Partner.
   c. The roles of the Academic and Sector partners are distinct and there is no real or perceived conflict of interest, or organization overlap.

3. **Impact:**
   c. How will the sector benefit by the proposed project (both directly and indirectly)?
   d. Would the project lead to adoption of the innovation in the sector?
   e. Will the project lead to socio-economic benefits for BC?

4. **Financials:**
   f. Has the Sector Partner committed the co-funding required to support the project?
   g. Does the committed co-funding meet the requirements as per Genome BC's Financial Guidelines in Appendix 2?

D. Program Parameters

GeneSolve projects budget and term:

- GeneSolve projects must have a minimum total budget of $100,000.
- Genome BC will award a minimum of $50,000 and up to a maximum of $250,000 per project, with at least a minimum 1:1 match from the Sector Partner.
- Project terms can range from 6 to 24 months.

Intellectual Property

Genome BC does not take an ownership stake in project intellectual property (IP); however, Genome BC expects a return on its investment in projects at affiliated BC research institutions, as defined by agreements between Genome BC and institutional partners.

E. Application Process

There is a two-stage application process for this program:

1. Expression of interest (EOI) outlining the scope of the proposed project to assess its eligibility and help identify reviewers; and
2. Application providing full details of the research plan with an accompanying budget and cofunding letter. There will also be a chance to Respond to Reviews in this step.

Expressions of Interest and applications must be submitted directly to Genome BC through the following email address: genesolve@genomebc.ca.

Expression of Interest

The EOI must provide a brief outline of the proposed project which addresses the eligibility criteria for GeneSolve. The EOI template is available on the Genome BC website (www.genomebc.ca) or by contacting Genome BC at genesolve@genomebc.ca.

EOIs must be submitted by the deadline posted by Genome BC to be considered for a particular intake. Each EOI will be reviewed by Genome BC to determine whether the project is eligible for the program. Teams will be informed about the results of their EOI about 4 weeks after the EOI deadline. Teams may be asked to resubmit their EOI to a future intake if there is insufficient information to assess eligibility. To avoid this, teams are encouraged to talk to a Genome BC Research and Innovation Manager before submitting an EOI.

Application

If invited to proceed in the program, teams can submit an application using the *GeneSolve Application Form*. Applications must address the evaluation criteria described in Appendix 1 of these Program Guidelines.

A companion Excel budget must be provided for the project along with a letter of cofunding commitment. Financial Guidelines are described in Appendix 2 of these Program Guidelines.

The application templates are available on the Genome BC website or by contacting Genome BC at genesolve@genomebc.ca.

Review Process and Outcomes

Applications will be assessed against the evaluation criteria described in Appendix 1 of these Program Guidelines. Each application will be sent for external written review by subject matter experts with expertise relevant to the application. Teams will be provided with written reviews and have the opportunity to respond to the main concerns raised by reviewers. Financial due diligence reviews will be conducted by Genome BC.

The proposal, reviews, and response from the team will go to Genome BC's GeneSolve review panel for discussion to determine a funding recommendation for each application. This review panel is composed of members with a relevant breadth of expertise including genomic sciences, assessing social or economic benefits, and expertise in relevant sectors. Final funding decisions will be made by Genome BC. Following the final decision process, all applicants, whether recommended for funding or not, will be provided with a summary of the review panel discussion and the external written reviews of their application.

Genome BC reserves the right to modify the review process if necessary to accommodate the number of applications received and ensure that the evaluation criteria and program objectives are met.

Successful applicants will receive a Notice of Results with conditions that must be met prior to project launch. Project-specific conditions may include the provision of additional supporting documentation or minor changes to the proposed project or budget.

In some cases, an application may not be approved as originally submitted, but the team may be invited to resubmit an application to a future intake of the program if the key concerns and/or recommendations can be addressed. For example, through changes to the research plan, project scope or methods. If invited to resubmit, the team will have the option to submit an application for their project to either of the next two GeneSolve intakes. Only one resubmission attempt will be accepted. Genome BC must receive email notification of the team's intent to resubmit by the intake's posted EOI deadline. The resubmitted application will go through the full review process; note that resubmission does not guarantee that the project will be approved for funding.

F. Genome British Columbia Contacts

Further information is available on the Genome BC website:
https://www.genomebc.ca/genesolve/

Interested applicants are encouraged to contact Genome BC at genesolve@genomebc.ca for information about the program or to discuss a potential application.

Appendix 1. Evaluation Criteria and Guidelines

To meet the objectives of GeneSolve, the following criteria will be used to evaluate the Proposal.

The following two categories of criteria are regarded as equally important:

A. Potential for impact on the sector

1. Would the project deliverables solve the challenge?
2. Are the deliverables realistic and achievable?
3. Are the proposed economic, social and/or environmental benefits of the research well-described and reasonable?
4. Have the potential users of the project outcomes been identified or engaged, as appropriate?
5. Is there a reasonable plan, appropriate to the stage of the innovation, to advance it beyond this project?

B. Research, Management and Financial Feasibility

Research

1. Will the genomics or genomics-derived approaches solve the challenge?
2. Are the major activities consistent between the research plan, budget and Gantt chart?
3. Does the proposed activities have specific, measurable objectives that will support the project deliverables?
4. Are the proposed objectives, goals, milestones and critical path feasible? Milestones must be constructed as to provide objective performance metrics and should be realistically attainable during the proposed timeframe.
5. Are the available resources, facilities and equipment suitable?
6. Are the design, methods and analysis adequately developed, well integrated, and appropriate to the aims of the project?
7. Does the project include collaborators that are essential to the success of the project?
8. Are the plans for handling the research data and biological resources (data protection, release and publication, resource sharing, etc.) appropriate?
9. Does the team have a risk management plan to mitigate potential risks (e.g., reasonable plan for sample collection or access to ensure the timely completion of the project)?

Management

10. Are the expertise and time commitment of the research team appropriate for realizing the project goals?
11. Does the project leader(s) have the demonstrated leadership and research expertise/experience?
12. Does the management plan cover project governance, accountabilities of personnel, and processes for decision making on project direction?

Financial

13. Do the budgeted costs comply with the eligible costs outlined in the Financial Guidelines (Appendix 2)?
14. Do the budgeted costs align with the proposed research plan and activities?
15. Are the financial and budgetary control processes effective?
16. Do the documentation and principal financial assumptions support the proposed budget?
17. Are the costs allocated to Genome BC incurred within BC? Costs incurred utilizing fee-for-service providers located outside of BC might be eligible subject to a quotation and strong justification as BC-based providers must be considered.
18. Is the company in a stable financial position allowing it to contribute to the project without concern? Can the company show there is no risk in their financial ability to see the project to the end?

Appendix 2. Financial Guidelines

A. Sector Partner funding

1. The Sector Partner must provide at least 50% of the approved funding for eligible project costs. For example, if the project budget is $400,000, then the Sector Partner must contribute at least $200,000.

2. Co-funding must be quantifiable and auditable.

Eligible Sector Partner Funding

1. For funds to be considered as cash, they must either be provided directly to the Academic Partner's institution or to an external, arms length third party for services that are incurred only for the proposed project. Such third party costs must be: new, fall within the project term, cannot be part of a previous contract, and the data/results of such third party services must be provided to the Academic Partner for use in the project. A strong justification must be provided to support why such costs cannot be incurred and paid for by the academic institution if being paid directly by the Sector Partner
2. All Sector Partner funds must flow directly to the institution and not through Genome BC.
    a. It is the project team's responsibility to coordinate flow of partner funds and negotiate any overhead fees with the institution. Supporting documentation for the overhead rate may be requested.
    b. Overhead fees are to be included in the project budget and can be classified as a consumable under a project management activity.
    c. Although a portion of the partner funds may be subject to institutional overhead fees, Genome BC will give full credit to the total cash sent to the institution (e.g. if the overhead fee for a $100,000 cash transfer is $10,000, Genome BC will still consider the original $100,000 as a partner cash contribution).
3. Eligible Sector Partner co-funding expenses may be recognized up to six months prior to Genome BC's Notice of Results subject to eligibility review.
4. All co-funding must be supported by appropriate documentation. This would include:
    a. Written confirmation (e.g. a letter or a legal agreement) from the co-funding source that commits the funds and provides details of the amount and date of funding, acknowledgment of the use of these funds to co-fund the Genome BC project and acknowledgment of compliance with Genome BC's reporting requirements. The co-funding letter cannot be signed by the Sector Partner leader.
    b. Co-funding from an industry source, including the Sector Partner:
        i. For privately held companies, a copy of a Board resolution specifying the company's amount and terms of commitment.
        ii. For larger companies, a letter from a senior signing authority who is independent to the project, specifying the company's amount and terms of commitment.
        iii. Documentation provided to support the financial viability of the organization and its ability to fulfill its commitment to the project, including recent financial statements accompanied by other information, such as cash flow projections,

audited financial statements, press releases announcing significant new funding, etc.

c. If applicable, a letter from the institution stating overhead fees relevant to the Sector Partner.

5. In-kind contributions can be as follows:

   a. Salaries and benefits of individuals that will carry out activities in the project excluding project leaders or co-leaders. These must be at cost with no mark up. Salaries may be for a new hire or the reassignment of an existing employee to work on the proposed GeneSolve project. If the person is being reassigned to the GeneSolve project, the organization would need to confirm in writing that they are re-allocating the individual to the GeneSolve project. The minimum time that an individual can be assigned to the project is 0.15 FTE per annum.

   b. Consumables must be accompanied by a clear rationale and calculation of how the value was determined and supported by documentation (e.g. assumptions, price lists, quotes from suppliers, third party letters supporting same, etc.).The matching Sector Partner co-funding cannot be composed of more than 15% consumables. That is, if the Sector Partner is contributing $100,000 in co-funding, no more than $15,000 can be related to consumables provided as in-kind co-funding.

   c. All in-kind expenditures must represent items that would otherwise have to be acquired with cash; however, this excludes the cost of pre-existing facilities or equipment (i.e. budgets cannot include the opportunity cost of space or equipment).

   d. Note that supplier discounts, including arrangements in which a supplier/purchaser relationship exists, are **not** acceptable sources of co-funding.

   e. G&A and equipment costs are **not** acceptable as in-kind co-funding expenditures.

   f. Genome BC may determine that only a portion of proposed in-kind contribution is eligible.

6. The value of previously existing IP transferred to a project is not eligible co-funding unless it is a contribution by a supplier of IP (e.g. software license that would otherwise have to be acquired from a third party supplier). Such items must be supported by appropriate documentation from the supplier's head office.

B. Eligible costs

Eligible costs are defined as reasonable and new costs for items that directly support the objectives of the Genome BC approved project. Note that Genome BC funds cannot flow to a company or to a provincial government laboratory unless they are providing the work on a Fee-for-Service basis (see Services from Others).

The main categories of eligible costs are: 1) salaries and benefits, 2) consumables, 3) services from others, 4) general and administrative costs and 5) equipment.

Eligible costs may include the following:

1. Salaries and benefits:

   a. Salaries for project team members, excluding Project Leader or Co-leaders, must represent at least 0.15 FTE per annum.

b. Benefits rate as charged by the host institution, not to exceed 20% of the employee's salary.

c. Salaries to support coordination of the project such as a Project Manager, to a maximum of $10,000 per year (pro-rated for part years) in total costs for projects.

d. Salaries for positions at a director level or higher require a strong justification for their inclusion.

2. Consumables:

   a. Materials and supplies consumed as part of the research, such as laboratory reagents and supplies (e.g. microtitre plates, pipette tips, kits, reagents). For consumables utilized in most laboratories, a general rate per Full Time Equivalent (FTE) may be accepted, provided that the rate is supportable and appropriately justified in the supporting documentation.

   b. Items that meet at least one of the following; 1) expendable tangible property, 2) useful life of 1 year or less, or 3) a cost of less than $2,000. For example, a $1,900 piece of equipment, such as a laptop, would be considered a consumable cost.

   c. Travel for research activities (e.g. sample collection).

   d. Equipment service contracts, provided that the equipment purchase is justified.

   e. Institutional overhead fee applied to the transfer of Sector Partner funds to the academic institution

3. Services from Others:

   a. External costs that are incurred based on a reasonable fee-for-service arrangement or contract.

   b. Costs related to Intellectual Property protection services such as patent registration, filing, and maintenance costs incurred during the term of the project, as long as the service is provided by a company external to the host institution.

   c. A copy of a quote or Statement of Work (SOW) must be attached to support any individual cost that exceeds $15,000. Quotes for services under $15,000 must be made available upon request.

   d. A strong justification must be made for the use of Genome BC funds for service providers located outside of BC.

4. General and Administrative (G&A)

   a. Reasonable general and administrative costs directly linked to the project such as: general office expenses, travel costs that are not directly related to the research activities (e.g. travel to conferences and meetings), costs for the project's communications and public outreach activities, and costs associated with scholarly publications, including fees to provide open access to the findings (e.g. costs of publishing in an open access journal or making a journal article open access).

   b. G&A costs must not exceed five percent (5%) of the non-administrative costs of the project budget (calculated as total budget less administrative costs).

5. Equipment:

   a. Equipment is defined as any item (or collection of interrelated items comprising a system) which is used wholly or in part for the research proposed and meets all three

of the following conditions: 1) non-expendable tangible property, 2) having a useful life of more than one (1) year, and 3) a cost of $2,000 or more.

b. A strong justification for the need to purchase equipment for a Genome BC project must be provided.

c. Any items of equipment over $15,000 require a copy of a quote to be attached with the application. Quotes or an equivalent document supporting the price for equipment under $15,000 must be made available upon request.

Ineligible costs include, but may not be limited to:

- indirect costs to the project, such as utilities, depreciation, accounting or administration (note that this is different from the institutional overhead charged by the institution on the transfer of Sector Partner funds)
- the opportunity cost of using existing infrastructure and equipment
- Project leader (Academic and Sector Partner) salary contributions
- costs related to the preparation and submission of an application for funding from Genome BC or any other funding agency.

Genome BC will conduct a financial due diligence review of each application and its associated budget as part of the review process to assess if costs are eligible and well justified.

Appendix 3. Technology Readiness Level (TRL) Scale

Technology Readiness Levels (TRL) are a type of estimation which can be used to assess the maturity level of a particular technology. There are nine technology readiness levels, starting with TRL 1 as the least mature and TRL 9 as commercially available. A TRL number is obtained once the description in the "Definitions of TRL Levels" table (see Table 1) has been achieved. For example, successfully achieving TRL 3 (proof-of-concept) does not automatically move the technology to TRL 4 until laboratory validation is underway.

Figure 1 Phases of Technology Readiness

Knowledge Development

TRL 1-3 is the **Research and Invention Phase** starting with initiation of scientific discovery research and ending with a proof-of-concept or feasibility model. This phase is mainly funded by public sources and work is performed in academic settings.

Technology Development

TRL 4-7 is the **Innovation Phase** which is attained once the proof-of-concept technology is ready and continues to the point where the technology has been demonstrated in an operational environment. At this stage, the technology and work may be transitioned from academia to public or private partnerships in anticipation of commercialization. It is in this phase that many new ideas going through the innovation process fail to progress. Those ideas that do succeed, can spend anywhere between 5-10 years or even longer in this phase.

Business Development

TRL 8 and 9 is the **Commercial Market Phase** in which technology has been tested, de-risked, qualified and is released into the market. Once proven, private organizations take the technology to the market and perform post-market release activities and surveillance.

Definitions of TRL Levels

Definitions and descriptions of each TRL have been adapted from multiple sources [1-7]. Below each level, comparable descriptions for genomics-related technology have been suggested.

Table 1 Definitions of Technology Readiness Levels used by Genome BC

Level	Description
TRL 1	Concept Evaluation - Basic principles observation and reporting
	• Review of scientific knowledgebase • Exploration of a technology's basic properties • Scientific findings are reviewed and assessed as a foundation for characterizing new technologies • Active review and analysis of scientific literature to identify rationale for a potential new product • Examples might include "paper studies" of a technology's basic properties
OMICS	• Literature searches and identification of existing resources (e.g. searching EST databases, SNP databases, etc.)

TRL 2	**Technology Evaluation** - Technology concept and/or application formulation
	• Study if and how a technology can produce improved outcomes compared to the *status quo*, or address an unmet need • Development of research ideas, hypotheses, experimental designs and protocols for addressing the related scientific issues • Use of computer simulation or other virtual platforms to test hypotheses • Examples are limited to analytical studies which focus on practical applications based on basic principles observed • Examples may also include screening of potential compounds or initial IP searches for patentability
OMICS	• Determining the value for sequencing a genome and planning for genome sequencing projects, such as deciding on which technology to use • Identifying potential pipeline components (i.e. for bioinformatics analysis) • Research idea, hypothesis, and experimental design generation through paper studies
TRL 3	**Proof-of-Concept Research** - Analytical and experimental critical function and/or characteristic proof of concept
	• Active R&D (research, data collection, and analysis) is initiated to test hypothesis, and a technological solution is developed • Identify what is required for a technology to meet the application's requirements • Explore prototypes, critical design features and components • Perform analytical and laboratory studies to physically validate the separate components which make up the technology • Develop standard operating protocols/procedures (SOPs) • Examples in drug development may include target and/or candidate identification, and characterization of preliminary candidate(s), including *in vitro* activity and preliminary i*n vivo* proof-of-concept (non-GLP) • Filing of IP would also be considered at this level
OMICS	• Library preparation and optimization, active sequencing, data collection (e.g. of WGS data), and running through candidate pipelines to determine the sequence and its quality, and evaluate the pipeline to be used
TRL 4	**Early-Stage Prototype Development** - Component and/or breadboard validation in laboratory environment (laboratory validation)
	• Iterative integration and testing of basic components and critical technologies (hardware and software) in a laboratory environment to establish that they will work together • Establish design and development plan, and develop a regulatory strategy • Examples include integration of *ad hoc* hardware into "low fidelity" prototypes in the laboratory • Examples also include initiation of experiments **to identify markers**, correlates of protection, assays, and endpoints for further non-clinical and clinical studies

OMICS	• Validation of WGS data and alignment using other resources such as optical maps, BAC-by-BAC sequencing, etc. to polish the sequence • Generation of a draft reference genome • Initial GWAS studies to determine if genotype-phenotype associations exist • Identification, selection and validation of relevant variants (SNPs) to be included on a panel • Assay/test method validation in accordance with the product's intended use (sample type, volume, assay components)
TRL 5	**Late-Stage Prototype Development** - Component and/or breadboard validation in relevant environment (field validation)
	• Integration and testing of basic components in a simulated environment usually involving accessing "better" testing equipment to identify potential issues • Significantly increased fidelity of breadboard technology • Begin (e.g. GLP) studies supporting regulatory requirements • Examples include drafting preliminary target product profiles, and determining properties such as shelf life, storage conditions, and packaging to ensure that anticipated use of the product is consistent with the intended use for which approval will be sought from regulatory authorities (e.g. FDA, Health Canada, CFIA)
OMICS	• Validate the genomic selection (predictive) models from GWAS to determine power of prediction • Validation of biomarkers or panels to predict organism and/or environmental status • Generation of high-quality reference genome, demonstration of the value of SNPs and arrays to obtain phenotypic data in the lab environment
TRL 6	**Simulated Environment Pilot** – System model or prototype demonstration in a relevant environment (field demonstration)
	• Final testing of representative model or prototype to provide data critical to the commercialization phase where the technology is applied • Represents a major step up in a technology's demonstrated readiness compared to TRL 5 • Regulated production, regulatory submission, and generation of clinical data • Examples include testing a prototype in a high-fidelity laboratory environment or in a simulated operational environment • Transfer or license of intellectual property by end user from academia
OMICS	• Pilot studies to confirm validity and utility of SNP panels and biomarkers in a clinical (non-laboratory) setting (e.g. early clinical trial)
TRL 7	**Operational Environment Demonstration** - System prototype demonstration in an operational environment (operational demonstration)
	• Prototype near or at planned operational system • Use of the prototype in an operational environment to understand how it performs in non-simulated testing • Requires demonstration of an actual system prototype in an operational environment (e.g., in an aircraft, in a vehicle, or in space) • Scale-up, initiation of GLP process validation • Validate assays for manufacturing quality control • Perform regulatory submissions for approval and marketing clearance

OMICS	• Utilization of reference quality genome, demonstration of the value of SNPs and arrays to obtain phenotypic data in the real world • Confirm clinical validity and utility of SNP panel and validation in a larger cohort
TRL 8	**Final Testing and Evaluation** - Actual system completed and qualified through test and demonstration (approval to market)
	• In most cases, TRL 8 represents the end of true system/product development • Technology has proven to be successful under normal operating conditions in its final form • Perform regulatory submissions of approved product to start marketing • Examples include developmental testing and evaluation of the product, or technology system in its intended use to ensure it meets design specifications
OMICS	• Product / diagnostic test is ready and approved for use for real world implementation, e.g. direct-to-consumer personal genomics testing
TRL 9	**Successful Deployment** - Actual system proven through successful mission operations
	• Market launch and post-market surveillance • Application of the technology, in its final form, in real-life "mission" conditions, such as those encountered in industry or clinical settings • Active sales and distribution, and post-marketing studies as may be required • Commence post-licensure/post-approval and post-marketing commitments, such as safety surveillance, and studies to support use of the technology/product in special populations
OMICS	• Post-commercialization and revenue generation activities • Post-market evaluation of relationships between particular genetic variations and the presence or absence of specific diseases or traits, and assessment of the interpretation of findings at a population level

Acronyms

R&D	Research and Development
WGS	Whole Genome Sequencing
GWAS	Genome-wide Association Studies
SNP	Single Nucleotide Polymorphism
IP	Intellectual Property
GLP	Good Laboratory Practice
FDA	United States of America, Food and Drug Administration
CFIA	Canadian Food Inspection Agency

Sources

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